



6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

APR -6 P3:25

March 20, 2000

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown') located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Organic Omega-3 Flax Oil 1000mg: [It] helps promote healthy cardiovascular and immune function. Thompson's Flax Oil, derived from the seeds of the flax plant, contains alpha-linolenic and linoleic acids, the two essential fatty acids needed by the body to help promote healthy cardiovascular and immune system function. Essential fatty acids are indispensable and must be supplied through the diet. They are components of cell membranes and are required for normal growth and development. A healthy diet requires the proper proportions of essential fatty acids. Flax Oil, containing a high ratio of alpha-linolenic to linoleic acid, helps enhance the levels of these fatty acids to improve their ratio.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Dink

Deborah Shur Trinker Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure